

REMARKS

Claims 1-43 are pending in the present application. Claims 40-43 are allowed. In light of the following remarks, applicants respectfully request reconsideration of this application and allowance of the pending claims to issue.

Rejection Under 35 U.S.C. § 112, first paragraph

The Office Action states that claim 39 is rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. Further stated in the Office Action is that the claim allegedly contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

According to the Office Action, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of mutants which could result in the claimed function, i.e. increased susceptibility for developing hypertension and therefore, conception is allegedly not achieved until reduction to practice as occurred, regardless of the complexity or simplicity of the method of isolation or identification. Also stated in the Office Action is that adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The Office concludes that the compound itself is allegedly required. Further stated in the Office Action is that even if one can perform a method of associating a mutant Cyp4A11 sequence with an increased susceptibility for developing hypertension, this does not meet the requirements for adequate written description of the invention as claimed. The Office Action goes on to state that the mere statement in the specification that one can carry out the step of associating a mutant Cyp4A11 sequence with an increased susceptibility for developing hypertension expresses a wish that such mutants may be

isolated, rather than an adequate description of such mutants.

Applicants respectfully point out that the present claims are method claims and not composition claims. The first paragraph of 35 U.S.C. § 112 requires "a written description of the *invention*." The invention is what is claimed. Claims can be drawn to various types of inventions, including, for example, claims to compositions *per se* and claims to methods. A composition is a physical object, which has a physical structure. A method is a process made up of one or more process steps (that is, one or more acts to be carried out). Thus, the written description of a composition invention typically requires at least some description of the structure of the composition (because a composition (structure) is what the invention is), and the written description of a method invention requires description only of the acts to be performed (because a method (acts) is what the invention is). This distinction is supported by the Written Description Guidelines, in which the first step in the analysis of compliance with the written description requirement is to "[d]etermine whether the application as filed describes the complete structure (*or acts of a process*) of the claimed invention as a whole." Written Description Guidelines at 1106 (emphasis added). Nothing in the statute or the case law requires a written description of anything other than the *claimed invention* for compliance with the written description requirement. Thus, only the process steps of a claimed method need be described in order to satisfy the written description requirement for a method and Applicants have adequately done so.

For example, the first step of claim 39 (step a) is detecting a mutant Cyp 4A11 polypeptide or a mutated Cyp 4A11 nucleic acid in the subject. Applicants respectfully point out that several methods of identifying mutations are provided on pages 37 and 38 of the specification. Furthermore, these methods and other methods of identifying mutations are considered routine. The wild-type sequence of Cyp4A11 is known and available to those of skill

in the art. Given that methods of identifying mutations are known and that the wildtype sequence of Cyp4A11 is readily available to those of skill in the art, it would be routine for one of skill in the art to detect a Cyp4A11 sequence that is different from the wildtype Cyp4A11 polypeptide or wildtype Cyp4A11 nucleic acid, i.e. a mutant Cyp 4A11 polypeptide or a mutated Cyp4A11 nucleic acid, in a subject. Therefore, there can be no question that the teachings of the specification combined with art recognized techniques that are extensively developed put one of skill in the art in possession of the step of detecting a mutant Cyp 4A11 polypeptide or a mutated Cyp 4A11 nucleic acid in the subject.

The next step in claim 39 (step b) is associating the mutant Cyp4A11 polypeptide or the mutated Cyp4A11 nucleic acid with an increased susceptibility for developing hypertension, thereby identifying a subject having an increased susceptibility for developing hypertension. Since step b) of claim 39 requires that one of skill in the art determine whether the mutation(s) detected in step a) is associated with an increased susceptibility for developing hypertension, it is not necessary to know *a priori* which mutation(s) will be found in a particular Cyp4A11 polypeptide or nucleic acid sequence of a subject or which mutation(s) are associated with an increased susceptibility for developing hypertension. One of skill in the art must simply be able to perform step b) in order to associate the mutant Cyp4A11 sequence detected in step a with an increased susceptibility for developing hypertension. As set forth above, written description of a method claim requires a description of the acts to be performed and Applicants have adequately described how to determine if a mutant Cyp4A11 polypeptide or mutant Cyp4A11 nucleic acid sequence is associated with an increased susceptibility for developing hypertension. As stated by Applicants on page 36, lines 18-21, “[b]y increased susceptibility for developing hypertension’ is meant a subject who has a greater than normal chance of developing hypertension, compared to the general population. Such subjects include, for example, a subject that harbors a mutation in a

Cyp4A11 gene such that biological activity of Cyp4A11 is altered.” Therefore, based on the teachings of the present invention, one of skill in the art can detect a mutant Cyp4A11 sequence and readily assess whether a mutation in a Cyp4A11 sequence results in altered biological activity. For example, one of skill in the art can assess the effects of a mutated Cyp4A11 on a subject’s blood pressure. Furthermore, it is also routine for one of skill in the art to utilize statistical analysis to determine if a mutant Cyp4A11 in a subject results in a greater than normal chance of developing hypertension, as compared to the general population. Therefore, there can be no question that the teachings of the specification combined with art recognized techniques that are extensively developed put one of skill in the art in possession of the step of associating the mutant Cyp4A11 polypeptide or the mutated Cyp4A11 nucleic acid with an increased susceptibility for developing hypertension. Thus, reading the specification in light of the knowledge and level of skill in the art, the specification discloses and puts one of skill in the art in possession of the complete steps of the claimed process (claim 39). Therefore, one skilled in the art would understand what is intended by the claimed invention and know how to carry it out. In other words, given Applicants’ discovery that mutations in Cyp4A11 sequences are associated with increased development of hypertension, the skilled artisan would immediately know that upon detecting any mutant Cyp4A11 sequence, they can determine whether or not this sequence is associated with an increased susceptibility for development of hypertension. If the mutant Cyp4A11 sequence is associated with an increased susceptibility for development of hypertension, the subject has an increased susceptibility for developing hypertension.

With regard to the Examiner’s statement that the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of mutants which could result in the claimed function, i.e. increased susceptibility for developing hypertension and that conception is not achieved until reduction to practice has occurred, Applicants respectfully remind the

Examiner that Applicants are not claiming the mutant Cyp4A11 sequences. It is clear that claim 39 is not directed to the Cyp4A11 mutant sequences, but instead to methods that require associating mutant Cyp4A11 sequences with an increased susceptibility for developing hypertension. As set forth above, the sequences used in a claimed method need not have this type of written description because only the “invention” need be described, *Vas-Cath v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1116-18 (Fed. Cir. 1991), and a method is an invention made up of process steps. Only the steps need be described, and the sequences used in a method need only be described so as to enable their use because only the enablement make and use requirement of 35 U.S.C. § 112, first paragraph, is implicated. Therefore, contrary to the Examiner’s assertion that the compound itself is required to adequately describe the method of claim 39, Applicants assert that the detailed chemical structure of a mutant Cyp4A11 sequence is not required for adequate written description of claim 39.

Also, contrary to the Examiner’s assertion that the mere statement in the specification that one can carry out the step of associating a mutant Cyp4A11 sequence with an increased susceptibility for developing hypertension expresses a wish that such mutants may be isolated, rather than an adequate description of such mutants, Applicants once again point out that the claims are not directed to the mutants themselves, but instead to methods involving the detection of Cyp4A11 mutants and their subsequent association with increased development of hypertension. As previously stated, Applicants were the first to discover mutant Cyp4A11 sequences that are associated with increased susceptibility to hypertension. Therefore, it is erroneous for the Examiner to state that Applicants have merely expressed a wish that such mutants may be isolated. It is clear from the specification that Applicants have isolated mutants associated with increased hypertension and have provided the necessary guidance for one of skill in the art to immediately envisage that any mutant Cyp4A11 could be associated with increased

hypertension. Given this knowledge, one of skill in the art would readily recognize that upon detection of a mutant Cyp4A11 sequence in a subject, this mutation can be associated with increased hypertension via routine methods, in order to identify subjects that have an increased susceptibility to developing hypertension.

Thus, Applicants believe that the method of claim 39 does not include a scope that the skilled person would view as outside of applicants' possession when the application was filed. Therefore, it would be clear to one of skill in the art that applicants were in possession of the invention as claimed. Thus, applicants believe this rejection has been overcome and respectfully request its withdrawal.

A Request for Extension of Time and a Card Payment Form PTO-2038 authorizing payment in the amount of \$225.00 representing the fee for a small entity under 37 C.F.R. § 1.17(a)(2) are enclosed. No additional fee is believed due. However, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,  
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**CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8**

I hereby certify that this AMENDMENT, and any item indicated as being attached or included, is being sent via first class mail to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.



Lizette M. Fernandez, Ph.D.

Date

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